

REMARKS

The Examiner is thanked for having graciously held an interview with Dr. Tim Creagan and the undersigned on June 23, 2005.

The application and the Office Action of May 18, 2005 were discussed. It was agreed that claim 85, 86, 88-91 and 93 be canceled without prejudice and that claim 87 be amended to recite an azithromycin mixture comprising substantially pure form F azithromycin and optionally azithromycin dihydrate. It was also agreed that the amended claim 87 cover substantially pure form F azithromycin as well as the mixture of substantially pure form F azithromycin and azithromycin dihydrate. As a result, any potential prior art reference against a claim on substantially pure form F azithromycin will also be considered against the amended claim 87 and all its dependent claims.

The Examiner and the undersigned discussed prior art references, such as U.S. Patent No. 6,365,574 ("the '574 patent"), issued to Singer et al. on April 2, 2002, which is now reissue application Serial No. 10/816,376, filed on April 2, 2004 (hereinafter "the '376 reissue application"). It was agreed that a 131 declaration could be filed to swear-behind the '574 patent or the '376 reissue application.

It was further noted that the '376 reissue application added a new claim 25 which reads "The azithromycin of claim 23, wherein the isolated azithromycin is substantially pure." However, the Examiner rejected new claim 25 of the '376 reissue application under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the terminology "substantially pure" (claim 25) is not described or suggested by the specification as originally filed. *See page 4 of the March 30, 2005 Office Action in the '376 reissue application.* The Examiner also rejected all other new claims of the '376 reissue application under 35 U.S.C. 112, first paragraph. The undersigned fully agree with the Examiner on her refusal to enter all new claims, including new claim 25, in the '376 reissue application for lack of support in its original specification. The undersigned also fully agree with the Examiner that there is no interfering subject matter IN FACT between the present application and the '376 reissue application because the new claims in the '376 reissue application are not entered and that all claims of the '376 reissue application are rejected.

With regard to the amendments to claim 87 in the present application, Applicants respectfully submit that such amendments are fully supported by the

original specification. Specifically, the present application described “substantially pure form F azithromycin” on page 2, line 22 of the original specification and defined the terminology “substantially pure” on page 5, lines 22-25 of the original specification as “referring to a designated crystalline form of azithromycin means that the designated crystalline form contains less than 20% (by weight) of residual components such as alternate polymorphic or isomorphic crystalline form(s) of azithromycin.” Furthermore, the amendments to claims 92 and 123 in the present application involve correcting informalities and changing claim dependency and do not raise any issue of new matter. Moreover, support for new claims 124-132 of the present application can be found, *inter alia*, on page 22, lines 15-18 of the original specification and also do not raise any issue of new matter. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 87, 92 and 123-132 will be under examination.

Applicants have also filed a Second Terminal Disclaimer on July 8, 2005 with regard to U.S. patent application No. 10/650,253 filed on August 27, 2003, U.S. patent application No. 10/652,933 filed on August 28, 2003, U.S. patent application No. 10/652,655 filed on August 28, 2003 and U.S. patent application No. 11/123,542 filed on May 6, 2005. Applicants note that the first Terminal Disclaimer with regard to U.S. Patent Application No. 10/152,106 was filed on April 12, 2005. Therefore, there should be no rejection based on judicially created doctrine of obvious-type double patenting.

A petition to correct inventorship will be filed shortly to change the inventorship from the joint inventorship of Zheng J. Li and Andrew W. Trask to the joint inventorship of Zheng J. Li, Andrew W. Trask and Joseph E. Mertz.

#### OBJECTION TO CLAIMS

Claims 92 and 93 are objected to for informalities. Applicants have amended claim 92 to correct the misspelled word and canceled claim 93 without prejudice. Therefore, this ground of objection is moot.

#### REJECTION OF CLAIMS UNDER 35 U.S.C. 102(a) AND/OR 35 U.S.C. 103(a)

Claims 85-87, 91 and 123 stand rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Bosch et al., U.S. Patent No. 6, 420,537 (“Bosch”).

Applicants have canceled claims 85, 86 and 91 without prejudice and amended claim 87 to emphasize that the azithromycin mixture comprising substantially pure form F azithromycin and optionally azithromycin dihydrate. In addition, claim 123 has been amended to be dependent upon claim 87.

Applicants will file a petition to correct inventorship to add Joseph Mertz as a co-inventor. Applicants also enclose a 131 Declaration from Joseph Mertz showing that the subject matter of claim 87 was reduced to practice prior to May 8, 1998, the priority date of Bosch. Therefore, Bosch is not a proper reference against claim 87, as amended. Accordingly, this ground of rejection is moot.

REJECTION OF CLAIMS UNDER 35 U.S.C. 102(a) AND/OR 35 U.S.C. 103(a)

Claims 85 and 123 stand rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Aronhime et al., U.S. Patent No. 6,586,576 ("Aronhime").

Applicants have canceled claim 85 without prejudice and amended claim 123 to be dependent upon claim 87. Therefore, this ground of rejection is moot.

REJECTION OF CLAIMS UNDER 35 U.S.C. 102(a) AND/OR 35 U.S.C. 103(a)

Claims 85 and 123 stand rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bayod Jasanada et al., U.S. Patent No. 6,450,990 ("Bayod").

Applicants have canceled claim 85 without prejudice and amended claim 123 to be dependent upon claim 87. Therefore, this ground of rejection is moot.

REJECTION OF CLAIMS UNDER 35 U.S.C. 103(a)

Claims 85-87 and 123 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al., U.S. Patent No. 6,365,574 ("the '574 patent") in combination with Bayod.

Applicants have canceled claims 85 and 86 without prejudice and amended claim 87 to emphasize that the azithromycin mixture comprising substantially pure form F azithromycin and optionally azithromycin dihydrate. As shown in the enclosed 131 Declaration from Joseph Mertz, the claimed subject matter in the amended claim 87 of the present application was reduced to practice prior to May 8, 1998 which is earlier than either April 2, 2002, the publication date of the '574 patent

or November 30, 1998, the earliest priority date of '574 patent. Therefore, the '574 patent is not a proper reference against claim 87, as amended. The '574 patent is also not a proper reference against the amended claim 123 and new claims 124-132 which are dependent upon claim 87, as amended. Accordingly, this ground of rejection is moot.

#### REJECTION OF CLAIMS UNDER DOUBLE PATENTING

Claims 85, 86 and 90 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,861,413 in view of Bayod.

Applicants have canceled claim 85, 86 and 90 without prejudice without prejudice. Applicants have also concurrently filed a Second Terminal Disclaimer with regard to U.S. patent application No. 10/650,253 filed on August 27, 2003, U.S. patent application No. 10/652,933 filed on August 28, 2003, U.S. patent application No. 10/652,655 filed on August 28, 2003 and U.S. patent application No. 11/123,542 filed on May 6, 2005. That is in addition to the first Terminal Disclaimer filed on April 12, 2005 with regard to U.S. Patent Application No. 10/152,106. Therefore, this ground of rejection is moot.

#### OBJECTION TO CLAIMS

Claims 88, 89, 92 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants have canceled claims 88, 89 and 93 and amended claim 92 to be dependent upon claim 87. As stated in Applicants' responses to 102(a)/103(a) rejections, claim 87, as amended, should be allowed, together with all its dependent claims. Therefore, this ground of objection is moot.

CONCLUSION

In view of the interview, the claim amendments, the terminal disclaimer and the remarks, further and favorable considerations of the presently pending claims are respectfully requested.

It is believed that no fee is required in connection with the present Amendment. However, if any fees are required, the Commissioner is authorized to charge such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

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Lance Y. Liu

**Customer No. 28523**  
Pfizer Inc.  
Patent Department, MS 8260-1611  
Eastern Point Road  
Groton, Connecticut 06340  
(860) 686-1652

Lance Y. Liu  
Attorney for Applicant(s)  
Reg. No. 45,379